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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,984	10/02/2003	Oliver B. Anderson	MCP5018	9054

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EXAMINER	
DAVIS, ROBERT B	
ART UNIT	PAPER NUMBER
1791	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/677,984	ANDERSON ET AL.	
	Examiner	Art Unit	
	Robert B. Davis	1791	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 7-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 7-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Response to Amendment

Allowable Subject Matter

1. The indicated allowability of claims 1-5 and 7-16 is withdrawn in view of the newly discovered reference(s) to Clarke et al (WO 03/020246 A1). Rejections based on the newly cited reference(s) follow.

Claim Objections

2. Claims 8-10, 14 and 15 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claims 8-10, 14 and 15 merely recite the materials being worked upon by the molding apparatus and do not further limit the structure of the apparatus. These claims should be canceled.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any

inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-4, 9-12, 14, 15 and 16 are rejected under 35 U.S.C. 103(a) as being obvious over Sowden et al (20030086973 A1: figures 26c, 27c, 28 and 32-35) taken together with Ihara et al (6,666,675: figures 1-2 and column 3, lines 14-20), Jenko (6,135,757: figures 7-8 and column 5, lines 8-21) and Clarke et al (WO 03/020246 A1: figures 1-4)

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in

accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Sowden et al disclose an injection molding machine for forming a coated dosage form comprising: a mold plate, a retention plate, the mold plate and retention plate defining a cavity which supports a core and having a flow path defined in part by an interior surface of the mold plate and the core to be coated; and a nozzle assembly for introducing flowable material into the mold cavity to encapsulate the core. The nozzle has a nozzle tip and a valve body having a valve stem tip. The claims are being interpreted to require the core in the mold cavity because of the language that the mold path is defined by the mold plate and the core. The reference does not disclose or suggest the valve stem tip or the nozzle tip being constructed of a thermally insulative material.

Ihara et al disclose an injection molding nozzle assembly having a nozzle tip (2) made of a low thermal conductivity metal which results in a nozzle assembly that prevents dropping, cob-webbing or the like out of the nozzle tip. The lower thermal conductivity material also allows for positive setting of the set temperature in the nozzle (1).

Jenko discloses a nozzle assembly having a valve stem (100) having a stem made of H-13 tool steel and a tip made of a titanium or ceramic material and affixed to the valve stem. The material of the tip is selected for wear and/or thermal characteristics. The teaching reference of Olaru clearly sets forth that titanium has a lower thermal conductivity than H13 tool steel.

Clarke et al disclose an injection molding apparatus comprising a mold tool (2) having opposing female molds (2A, 2B) having projections (4) for centering a core (1) of a dosage form such that a flowable material is injected into a gate (5) to fill the cavity (3) to form a composite dosage form as illustrated in figure 4 that has an opening in the coating material (6) to the inner core (1).

It would have been obvious at the time of the invention to one of ordinary skill in the art to modify the apparatus of Sowden et al by selecting a nozzle tip of a lower thermal conductivity material as disclosed by Ihara et al for the purpose of reducing dropping or cob-webbing of the polymer from the nozzle tip. Such dropping and cob-webbing result in unwanted polymer material being discharged from the nozzle.

It would have been obvious at the time of the invention to one of ordinary skill in the art to modify the apparatus of Sowden by selecting the valve stem tip from a material having a lower thermal conductivity than the valve stem as disclosed by Jenko for the purpose of reducing unwanted heat transfer between the mold and the nozzle assembly.

It would have been obvious at the time of the invention to one of ordinary skill in the art to modify the apparatus of Sowden et al by providing the mold cavity with projections as disclosed by Clarke et al for the purpose of accurately positioning the core of a dosage form within the mold cavity and to form an opening in the coating material.

6. Claims 5, 8 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sowden et al taken together with Ihara et al, Jenko and Clarke

et al as applied to claims 1-4, 9-12 and 14-16 above, and further in view of Zoppas (WO 03/045662 A1: figure and page 4, lines 1-16).

The previous combination discloses all claimed features except for the valve stem tip and the nozzle tip being constructed of thermally insulative polymer.

Zoppas disclose a gasket assembly of an injection molding nozzle being made of a polyamide, polytetrafluoroethylene or polyetherketone compound.

It would have been obvious at the time of the invention to one of ordinary skill in the art to modify the apparatus of the previous combination by substituting the thermally insulative polymer compounds of Zoppas for the lower thermal conductivity materials of Ihara et al and Jenko because the use of thermally insulative polymers was well known in the injection molding art as illustrated by Zoppas and one of ordinary skill in the art would expect them to work at least as well as the materials of the lower thermal conductivity materials of the previous combination based upon the environment in which the polymers are used by Zoppas.

7. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sowden et al taken together with Ihara et al, Jenko and Clarke et al as applied to claims 1-4, 9-12 and 14-16 above, and further in view of Myllymaki (4,289,191: figure 3 and column 4, lines 35-47).

The previous combination discloses all claimed features except for the projections to be spring biased.

Myllymaki disclose a mold for injection molding a composite article comprising opposing female molds (22, 24) having locating pins (38') which are spring loaded such that the pins are flexible to support preforms of variable sizes without breaking the preform.

It would have been obvious at the time of the invention to one of ordinary skill in the art to modify the apparatus of the previous combination by spring loading the projections as disclosed by Myllymaki for the purpose of accommodating preforms of varying sizes without damaging the preform.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B. Davis whose telephone number is 571-272-1129. The examiner can normally be reached on Monday-Friday 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yogendra Gupta can be reached on 571-272-1316. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert B. Davis/
Primary Examiner, Art Unit 1791
February 26, 2008